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	A THAT IS		Applic	ation Number	.10/549,545
TRANSMITTAL			Filing	Date	May 26, 2006
FORM			First I	lamed Inventor	Matteucci
(to be used for all co	rrespondence after in	itial filing)	Group	Art Unit	1626
			Exami	ner Name	Unassigned
Total Number of Page	s in This Submission	7	Attorn	ey Docket Number	021305-003900US
		ENCLO	OSURES	(check all that apply)	·
Fee Transmittal F	-orm	Assign	ment Par Application	pers	After Allowance Communication to Group
Fee Attached	ı	☐ Drawin	g(s)		Appeal Communication to Board of Appeals and Interferences
Amendment / Res	sponse	Licensi	ng-relate	d Papers	Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
After Final		and Ad	company	Slip (PTO/SB/69) ving Peุtition	Proprietary Information
☐ Affidavits/dec	laration(s)		to Conv onal App		Status Letter
			wer of Attorney, Revocation ange of Correspondence Address		Other Enclosure(s) (please identify below):
Express Abandonment Request			nal Disclaimer est for Refund		Return receipt postcard Twenty-Nine (29) references
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Firm	Townsend and Tov	vnsend and	Crew LLF		
and Individual name	Randolph Ted App	le 		Reg No.	36,429
Signature	Ke			<u>.</u>	
Date	November 16, 200	6			
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I hereby certify that the class mail in an envel	nis correspondence is lope addressed to: C	being depo ommissione	sited with for Pate	the United States Postants, P.O. Box 1450, Alex	al Service with sufficient postage as first candria, VA 22313-1450 on this date: November 17, 2006
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Mark MATTEUCCI et al.

Application No.: 10/549,545

Filed: May 26, 2006

For: COMPOSITIONS AND METHODS

FOR TREATING CANCER

Confirmation No.: 1659

Examiner: Unassigned

Art Unit: 1626

INFORMATION DISCLOSURE

STATEMENT UNDER 37 CFR §1.97 and

§1.98

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

The references cited on the attached PTO/SB/08A and PTO/SB/08B forms are being called to the attention of the Examiner. Copies of the references [in compliance with the requirements of 37 CFR §1.98(a)(2)] are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR 1.97(g) and (h), no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant

Mark MATTEUCCI et al. Application No.: 10/549,545

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information, and no inference should be made that the information and references cited are, or are considered to be material to patentability because they are in this statement. No inference should be made that the information and references cited are prior art merely because they are in this statement.

Applicant believes that <u>no fee is required</u> for submission of this statement. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

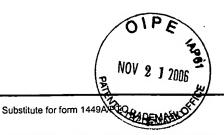
Respectfully submitted,

Randolph Ted Apple Reg. No. 36,429

TOWNSEND and TOWNSEND and CREW LLP Two Embarcadero Center, Eighth Floor San Francisco, California 94111-3834

Tel: 650-326-2400 Fax: 650-326-2422

RTA:crf 60917705 v1



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Sheet

Complete if Known			
Application Number 10/549,545			
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Examiner Name	Unassigned		
Attorney Docket Number	021305-003900US		

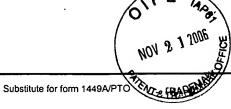
Examiner	Cite	Document Number	U.S. PATENT DO Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
Initials*	Cite No.1	Number Kind Code ^{2 (# known)}	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
	AA	US-6,855,695	02-15-2005	Xu et al.	
	AB	US-6,656,926	12-02-2003	Borch et al.	
	AC	US-6,251,933	06-26-2001	Denny et al.	
April 1977	AD	US-6,130,237	10-10-2000	Denny et al.	
	AE	US-6,020,315	02-01-2000	Bosslet et al.	
***************************************	AF	US-5,985,909	11-16-1999	Denny et al.	
	AG	US-5,877,158	03-02-1999	Bosslet et al.	
	AH	US-5,872,129	02-16-1999	Denny et al.	
***************************************	Al	US-5,780,585	07-14-1998	Anlezark et al.	
	AJ	US-5,750,782	05-12-1998	Denny et al.	
***************************************	AK	US-5,703,080	12-30-1997	Nakakura et al.	
***************************************	AL	US-5,622,936	04-22-1997	Wiessler et al.	
	AM	US-5,472,956	12-05-1995	Borch et al.	
	AN	US-5,403,932	04-04-1995	Borch et al.	
***************************************	AO	US-5,306,727	04-26-1994	Borch et al.	
······································	AP	US-5,190,929	03-02-1993	Borch et al.	
	AQ	US-4,921,963	05-01-1990	Skov et al.	
	AR	US-4,908,356	03-13-1990	Borch et al.	
	AS	US-3,652,579	03-28-1972	Hoffer et al.	
	AT	US-2005/0043244 A1	02-24-2005	Lin et al.	
	AU	US-2004/0254103 A1	12-03-2004	. Xu et al.	
	AV	US-2004/0176332 A1	09-09-2004	· Borch et al.	
	AW	US-2004/0121940 A1	06-24-2004	De Groot et al.	***************************************
	AX	US-2003/0130189 A1	07-10-2003	Sender et al.	
	AY	US-2003/0096743 A1	05-22-2003	Sender et al.	
	ΑZ	US-2003/0050331 A1	03-13-2003	Ng et al.	***************************************
	ВА	US-2003/0008850 A1	01-09-2003	Borch et al.	

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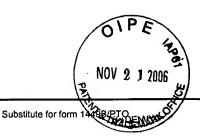
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Sheet 2 of 4

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Attorney Docket Number	021305-003900US		

	FOREIGN PATENT DOCUMENTS							
Examiner Cite		Foreign Patent Document			Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages	
Initials*	No.¹	Country Code ³	Number ⁴	Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	or Relevant Figures Appear	
	BB	DE	2229223		02-15-1973			
	BC	EP	648 503	- A1	04-19-1995			
	BD	wo	04/85421	A2	10-07-2004			
	BE	wo	04/85361	A1	10-07-2004			
	BF	wo	02/96910	A1	12-05-2002	•		
	BG	wo	00/64864	A1	11-02-2000	•		

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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NON PATENT LITERATURE DOCUMENTS T^2 Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, Examiner Cite magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city Initials 1 No.1 and/or country where published. BERRY et al., "5-Nitrofuran-2-ylmethyl group as a potential bioreductively activated pro-drug system," J. Chem. ВН Soc. Perkin Trans., 1:1147-1156 (1997). BORCH et al., "Synthesis and Evaluation of Nitroheterocyclic Phosphoramidates as Hypoxia-Selective Alkylating Agents," J. Med. Chem., 43:2258-2265 (2000). BORCH et al., "Antitumor Activity and Toxicity of Novel Nitroheterocylic Phosphoramidates," J. Med. Chem., BJ44:74-77 (2001). DE GROOT et al., "Anticancer Prodrugs for Application in Monotherapy: Targeting Hypoxia, Tumor-Associated BK Enzymes, and Receptors," Current Medical Chemistry, 8:1093-1122 (2001). DE JAEGER et al., "Relationship of hypoxia to metastatic ability in rodent turnours," Br. J. Cancer, 84(9):1280-BL ENGLE et al., "31P NMR Kinetic Studies of the Intra- and Intermolecular Alkylation Chemistry of Phosphoramide Mustard and Cognate N-Phosphorylated Derivatives of N, N-Bis(2-chlorethyl)amine^{1,2}," J. Med. Chem., 25:1347-BM 1357 (1982). EVERETT et al., "Modifying rates of reductive elimination of leaving groups from indolequinone prodrugs: a key BN factor in controlling hypoxia-selective drug release," Biochemical Pharmacology, 63:1629-1639 (2002). EVERETT et al., "Bioreductively-Activated Prodrugs for Targeting Hypoxic Tissues: Elimination of Aspirin from BO 2-Nitroimidazole Derivatives," Biooganic Med. & Chem. Ltrs., 9:1267-1272 (1999). HAY et al., "A 2-Nitroimidazole Carbamate Prodrug of 5-Amino-1-(Chloromethyl)-3-[(5,6,7-Trimethoxyindol-2-YL)Carbonyl]-1,2-Dihydro-3H-Benz[E]Indole (Amino-Seco-CBI-TMI) for Use With Adept and Gdept," RP Biooganic Med. & Chem. Ltrs., 9:2237-2242 (1999). HAY et al., "Structure-Activity Relationships of 1,2,4-Benzotriazine 1,4-Dioxides as Hypoxia-Selective Analogues во of Tirapazamine," J. Med. Chem., 46:169-182 (2003). HERNICK et al., "Design, Synthesis, and Biological Evaluation of Indolequinone Phosphoramidate Prodrugs BR Targeted to DT-diaphorase," J. Med. Chem., 45:3540-3548 (2002). HERNICK et al., "Studies on the Mechanisms of Activation of Indolequinone Phosphoramidate Prodrugs," J. Med BS Chem., 46:148-154 (2003).

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	NON PATENT LITERATURE DOCUMENTS					
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²			
	BT	KYLE et al., "Direct Assessment of Drug Penetration into Tissue Using a Novel Application of Three-Dimensional Cell Culture," Cancer Research, 64:6304-6309 (2004).				
	BU	LIN et al., "(o- and p- Nitrobenzyloxycarbobyl) -5-fluorouracil Derivatives as Potential Conjugated Bioreductive Alkylating Agents," J. Med. Chem., 29:84-89 (1986).				
	BV	NAYLOR et al., "Recent Advances in Bioreductive Drug Targeting," Mini Reviews in Med. Chem., 1:17-29 (2001).				
	BW	PAPOT et al., "Design of Selectively Activated Anticancer Prodrugs: Elimination and Cyclization Strategies," <u>Curr. Med. Chem Anti-Cancer Agents</u> , 2:155-185 (2002).				
	вх	PARVEEN et al., "2-Nitroimidazol-5-Ylmethyl as a Potential Bioreductively Activated Prodrug System: Reductively Triggered Release of the Parp Inhibitor 5-Bromoisoquinolinone," Biooganic Med. & Chem. Ltrs., 9:2031-2036 (1999).				
	ВҮ	ROFSTAD et al., "Hypoxia-induced metastasis of human melanoma cells: involvement of vascular endothelial growth factor-mediated angiogenesis," <u>Br. J. Cancer</u> , 80(11):1697-1707 (1999).				
	BZ	ROSEN et al., "Phase 1 Study of TLK286 (Telcyta) Administered Weekly in Advanced Malignancies," Clin. Cancer Res., 10:3689-3698 (2004).				
	CA	STEINBERG et al., "Synthesis and Evaluation of Pteroic Acid-Conjugated Nitroheterocyclic Phosphoramidates as Folate Receptor - Targeted Alkylating Agents," <u>J. Med. Chem.</u> , 44:69-73 (2001).				
	СВ	WAKSELMAN, M., "1,4- and 1,6- Eliminations from Hydroxy- and Amino-Substituted Benzyl Systems: Chemical and Biochemical Applications," Nouv. J. Chim., 7(7):439-447 (1983).				
	СС	WEST et al., "A comparison of adriamycin and mAMSA, II. Studies with V79 and human tumour multicellular spheroids," Cancer Chemother. Pharmacol., 20:109-114 (1987).				
	CD	WORKMAN et al., "The experimental development of bioreductive drugs and their role in cancer therapy," <u>Cancer and Metastasis Rev.</u> , 12:73-82 (1993).				

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